UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,756	03/04/2002	Charles K. Chiu	PC9942C	8726

7590 04/26/2004

Paul H. Ginsburg
Pfizer Inc.
235 East 42nd Street, 20th Floor
New York, NY 10017-5755

EXAMINER	
ROBINSON, BINTA M	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 04/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,756	CHIU ET AL.	
	Examiner	Art Unit	
	Binta M. Robinson	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 8-11 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 8-11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

The examiner acknowledges the applicant's appeal brief filed 12/03.

The finality of the office Action is withdrawn at paper no. 6 in view of the new evidence submitted in the brief.

The brief has been treated as an argument/response to the rejection at paper no. 6.

Claims 8-11 are pending in the case.

The 112, first paragraph rejections of claims 8-11 and the 112, second paragraph rejection of claim 8 made at paper no. 6 are withdrawn in light of the evidence submitted in applicant's brief.

(New rejections)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8-11 are rejected under 35 U. S. C. 103(a) as being unpatentable over Allen. (See Reference N) in view of Chiu (See Reference O). Allen et. al. teaches the instant compound, of formula II, where B is t-Butyl, or (C1-C6) alkyl . At page 4, see the compound of formula II.

The difference between the prior art compound and the instantly claimed compounds is the teaching of a generic compound versus a disclosed species. Chiu et. al. teaches that the instant trovafloxacin compound in the instant claim 10 can be synthesized by reacting the instant compound of formula V with the instant compound of formula IV the instant trovafloxacin compound. See Claim 5 in the Chiu reference. In view of the Chiu process, it would have been obvious to one of ordinary skill in the art to select various known radicals within a genus to prepare structurally similar compounds. Accordingly, the compounds and process of preparing the trovafloxacin are deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed compounds and process over those of the generic prior art compounds and process.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 10 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 6066647. Although the conflicting claims are not identical, they are not patentably distinct from each other

because the U.S. Patent No. 6066647 teaches a method of forming a protonated form of the instant compound of formula VIII via an amine deprotection of the compound of formula II wherein B is t-butyl and (C1-C6)alkyl and A is an amine proteting group selected from t-butyloxycarbonyl, benzyloxycarbonyl, (C1-C6)alkylcarbonyl.

The difference between the prior art process and the instantly claimed process is the generic teaching of forming a protonated form of the instant compound of formula VIII via an amine deprotection agent versus the instant teaching of the hydrolysis of the instant compound of formula VI with methanesulfonic acid to form the compound of formula VIII, where the amine moiety of the compound is not further protonated. Kiso et. al., teaches that methanesulfonic acid is a deprotecting agent for N-protected moieties. (See Kiso, reference U). In view of Kiso, it would have been obvious to deprotect the instant compound of formula VI via hydrolysis with monomethanesulfonic acid to form the unprotonated form of the compound of formula VIII. Accordingly, the process is deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed process over those of the U.S. Patent No. 6066647.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 11 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6194424. Although the conflicting claims are not identical, they are not patentably distinct from each other because U.S. Patent No. 6194424 teaches an that alatrofloxacin mesylate is a prodrug of the instant compound trovafloxacin, which is made in the instant claim 9 whereas the instant application teaches a prodrug of trovafloxacin in claim 11, wherein the amino and carboxyl ends of the trovafloxacin are protected. The difference between the prior art compound and the instantly claimed compounds is the teaching of a an amino protected prodrug of trovafloxacin in the U.S. Patent No. 6194424 versus the teaching of a prodrug of trovafloxacin where both the amino and carboxyl moieties are protected. Bundgaard et. al., teaches that N-acylation is a promising way of obtaining prodrugs for other compounds such as allopurinol. See Reference U, page 29. In the instant compound of formula VI in claim 11, the amine moiety is protected with an acetyl group and the carboxyl moiety of the compound is protected with an alkyl group. In view of Bundgaard et. al. ,(See Reference V) it would have been obvious to one of ordinary skill in the art to synthesize a prodrug of trovafloxacin where both the amine moiety and the carboxyl moiety rather than just the amine moiety is protected. Accordingly, the compounds are deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed compounds over those of the U.S. Patent No. 6194424 compounds.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 11 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5164402. Although the conflicting claims are not identical, they are not patentably distinct from each other because 5164402 teaches N-protected trovafloxican compounds which are obvious over the instant acyl protected compounds where both the amino moiety and the carboxyl moiety of trovafloxacin are protected. The difference between the prior art compound and the instantly claimed compounds is the teaching of a an amino protected form of trovafloxacin in the U.S. Patent No. 5164402, in claim 1 wherein R1 is (C-1C6) alkyl, Y is o, p-difluorophenyl, W is hydrogen, R2 is the ring depicted where R3, R6, R9 and R25 are hydrogen, and R7 is NHCH3 or NHC2H5 versus the teaching of a form of trovafloxacin where both the amino and carboxyl moieties are protected. It would have been obvious to one of ordinary skill in the art to synthesize a prodrug of trovafloxacin where both the amine moiety and the carboxyl moiety rather than just the amine moiety is protected. Accordingly, the compounds are deemed unpatentable therefrom in the

absence of a showing of unexpected results for the claimed compounds over those of the U.S. Patent No. 5164402 compounds.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable Brighty et. al. (US Patent 5164402) in view of Bundgaard. (See Reference D).

Brighty claimed the drug of the instant claims (see claim 1 when R7 is NH2, R1 is H) and disclosed the diprotected compound and the process of making the instant claimed compound(See CAS attached, RN 13575-66-9, see copies attached) and see '402, col. 56-57, ex. 12. The diprotected compound of the claimed free amino or acid drug is the prodrug form of such drug (See Bundgaard). The difference between the Brighty '402 prodrug and the instantly claimed prodrug is that instead of the t-butoxyl prodrug at the amino functional group, the instant claim is drawn to an acyl prodrug of the amino functional group. N-acyl or N-acyloxy are optional choices for such prodrug preparation. (See Bundgaard, p. 33) One having ordinary skill in the art is deemed to be aware of all the prodrug forms conventional to the art. The replacement of one prodrug with a conventional alternative expected to operate in a similar manner is prima facie obvious in the absence of unexpected results.

2. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 8 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 8 of copending Application No. US 1998-71601P (See Reference U). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 9 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 9 of copending US Application No. 1998-7160P. Although the conflicting claims are not identical, they are not patentably distinct from each other because US Application No. 1998-7160P is claiming a process comprising hydrolysis of the instant compound of formula VI with methanesulfonic acid, water and an organic solvent to form a monomethanesulfonic acid salt of the compound of formula VII.

The difference between the US Application No. 1998-7160P process and the instantly claimed process is the teaching of a process in the U.S. Patent No. 1998-7160P that is occurring according to the process of claim 8, where another product, the compound of formula VI is being formed. It would have been obvious to one of ordinary skill in the art further refine a process of forming a compound of formula VI, whereby a compound of formula VI is reacted with with methanesulfonic acid, water and an organic solvent to form a monomethanesulfonic acid salt of the compound of formula VII. . Accordingly, the instant process is deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed process over those of the U.S. Patent No. 1998-7160P process.

4. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in

scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 8 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 8 of copending Application No. US 1998-71601P. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 10 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 10 of copending US Application No. 1998-7160P. Although the conflicting claims are not identical, they are not patentably distinct from each other because US Application No. 1998-7160P is claiming a process comprising hydrolysis of the instant compound of formula VI with methanesulfonic acid, and R3OH wherein R3 is C1-C6-alkyl to form the monomethanesulfonic acid salt of the instant compound of formula VIII.

The difference between the US Application No. 1998-7160P process and the instantly claimed process is the teaching of a process in the U.S. Patent No. 1998-

7160P that is occurring according to the process of claim 8, where another product, the compound of formula VI is being formed. It would have been obvious to one of ordinary skill in the art further refine a process of forming a compound of formula VI, whereby a compound of formula VI is reacted with methanesulfonic acid, and R3OH wherein R3 is C1-C6-alkyl to form the monomethanesulfonic acid salt of the instant compound of formula VIII. Accordingly, the instant process is deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed process over those of the U.S. Patent No. 1998-7160P process.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is 571-272-0692. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at 571-272-0699.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone numbers are

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45AM to 4:45PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4242, (703) 305-3592, and (703) 305-3014.

BMR

**BMR*

4/7/04

CEILA CHANG
PRIMARY EXAMINER
GROUP 1200 1625